

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: James C. KENNEDY et al.

Title: PHOTOCHEMOTHERAPEUTIC METHOD USING 5-

AMINOLEVULINIC ACID AND OTHER PRECURSORS

OF ENDOGENOUS PORPHYRINS

Appl. No.: 10/663,992

Filing Date: 09/17/2003

Examiner: Unassigned

Art Unit: 1614

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.56

Mail Stop PATENT APPLICATION Commissioner for Patents PO Box 1450 Alexandria, Virginia 22313-1450

Sir:

Applicants submit herewith on Form PTO/SB/08 a listing of the documents cited by or submitted to the U.S. PTO in parent application Serial No. 09/928,505, filed 08/14/2001. As provided in 37 CFR §1.98(d), copies of the documents are not being provided since they were previously submitted to the United States Patent & Trademark Office in the above-identified parent application.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

RELEVANCE OF EACH DOCUMENT

The relevance of the listed documents is explained in the parent application.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Data

FOLEY & LARDNER LLP

Customer Number: 22428

Telephone: Facsimile:

(202) 672-5475

March 2004

(202) 672-5399

Respectfully submitted,

Beth A. Burrous

Attorney for Applicants

Registration No. 35,087

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control

Substitute for form 1449B/PTO	Complete if Known		
MIFORMATION DISCLOSURE	Application Number	10/663,992	
,2004 S是ATEMENT BY APPLICANT	Filing Date	09/17/2003	
MAR 1 Det Submitted: March 11, 2004	First Named Inventor	James C. KENNEDY	
L)	Group Art Unit	1614	
e as many sheets as necessary)	Examiner Name	Unassigned	
Sheet 1 of 4	Attorney Docket Number	067286-0275	

				U.S. PATENT DOCUMENTS	3	
Examiner	Cite No.1	U.S. Patent De	ocument	Name of Patentee or Applicant of Cited Document	Date of Publication of	Pages, Columns, Lines,
Initials*	NO.	Number	Kind Code ² (if known)	Cited Document	Cited Document MM-DD-YYYY	Where Relevant Passages or Relevant · Figures Appear
	A1	4,772,681		FUKUDA, et al.	09/1988	
	A2	4,925,736		SHIKOWITZ	05/1990	
	A3	4,932,934		DOUGHERTY, et al.	06/1990	
	A4	4,977,177		BOMMER, et al.	12/1990	
	A5	5,004,811		BOMMER, et al.	04/1991	
	A6	5,079,262		KENNEDY, et al.	01/1992	
	A7	5,127,938		REBEIZ	07/1992	
	A8	5,163,990		REBEIZ	11/1992	
	A9	5,200,427		REBEIZ, et al.	04/1993	
	A10	5,211,938		KENNEDY, et al.	05/1993	
	A11	5,219,878		RINGUET, et al.	06/1993	
	A12	5,234,940		KENNEDY, et al.	08/1993	
	A13	5,226,907		TANKOVICH	07/1993	
	A14	5,422,093		KENNEDY, et al.	06/1995	
	A15	5,423,803		TANKOVICH, et al.	06/1995	
	A16	5,425,728		TANKOVICH	06/1995	
	A17	5,484,803		RICHTER	01/1996	
	A18	5,705,518		RICHTER ET AL.	01/1998	

	FOREIGN PATENT DOCUMENTS										
Examiner Initials*	Cite No. ¹	Fore Office ³	eign Patent De Number⁴	ocument Kind Code (if known)	- 1	Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Τ ⁶		
	A19	ΕP	0 233 701				08/1987				
	A20	WO	91/01727				02/1991		Ì		
	A21	WO	93/08715				05/1993		i		
	A22	wo	93/20810				10/28/1993				
	A23	WO	94/106424				03/31/1994				
	A24	WO	94/12239				06/09/1994				
	A25	WO	95/07077				03/1995		•		
	A26	WO	95/05813				03/02/1995				
	A27	wo	95/31189				11/23/1995				

NON PATENT LITERATURE DOCUMENTS							
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T 6				

Examiner Signature	Date Considered	
	1	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.

Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

MODIFIED PTO/SB/08 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control

	Substitute fo	r form 1449B	/PTO	Complete if Known			
	INFORMATION	ON DISCLO	SURE	Application Number	10/663,992		
	STATEMENT	ΓBY APPLI	CANT	Filing Date	09/17/2003		
	Date Submitte	nd: Morah 1:	1 2004	First Named Inventor	James C. KENNEDY		
	Date Submitte	eu. Marcii i	1, 2004	Group Art Unit	1614		
	(use as many s	heets as ne	cessary)	Examiner Name	Unassigned		
Sheet	2	of	4	Attorney Docket Number	067286-0275		

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T 6
	A28	BOEHNCKE, et al., Treatment of Psoriasis by Topical Photodynamic Therapy with Polychromatic Light, <i>The Lancet</i> , 343:801, March 1994.	
	A29	FUKUDA et al., Photodynamic Action of Endogenously synthesized Porphyrins from Aminolevulinic, <i>Int. J. Biochem.</i> , 25:10; 1395-98, 1993.	
	A30	LOH et al., Endogenous Porphyrin Distribution-Induced by 5-Aminolaevulinic Acid, <i>J. Photochem. Photobiol.</i> , 20:47-54, 1993.	
	A31	VAN DER VEEN et al., In Vivo Fluorescence Kinetics and Photodynamic Therapy Using 5-Aminolaevulinic. Br. J. Cancer, 70:867-72, 1994.	
	A32	GRANT et al., Photodynamic Therapy of Normal Rat Arteries After Photosensitisation Using, <i>Br. J. Cancer</i> , 70:72-78, 1994.	
	A33	KENNEDY, "Photochemotherapy - Clinical Aspects", Department of Oncology and Pathology, Photosensitisation. Edited by G. Moreno et al., pp. 453-463, (1988).	
	A34	KENNEDY, "Photodynamic Therapy With Endogenous Protoporphyrin IX: Basic Principles And Present Clinical Experience", <i>Journal of Photochemistry and Photobiology, B: Biology</i> , Vol. 6:143-148, (1990).	
	A35	DENNIS et al., "Protection of NIH 3T3 Cells From Infection By Trypomastigotes And Sphaeromastigotes Of J. Trypanosoma Cruzi, Telahuen Strain, By Porphyrins In The Presence And Absence of Light (630 and 690 NM)", Parasitol., Vol. 75(6):970-976, (1989).	
	A36	BERLIN et al., "Normal Pathways, Studied With The Aid of N", <i>The Metabolism of ä-Aminolaevulic Acid</i> , Vol.64:80-99,(1956).	
	A37	BRAULT et al., "Fundamental Aspects In Tumor Photochemotherapy: Interactions Of Porphyrins With Membrane Model Systems And Cells", <i>Biochimie</i> , Vol. 68:913-921, (1986).	
	A38	DIVARIS et al., "Phototoxic Damage To Sebaceous Glands And Hair Follicles Of Mice After Systemic Journal Administration of 5-Aminolevulinic Acid Correlates With Localized Protoporphyrin IX Fluorescence", <i>American of Patbology</i> , Vol. 136(4):891-897, (1990).	
	A39	GROSSMAN, "PDT For Hirsutiem", Lasers Surg. Med. Suppl., Vol. 7:A205, (1995).	
	A40	MALIK et al., "Topical Appliction of 5-Aminolevulinic Acid, DMSO and EDTA: Protoporphyrin IX Accumulation In Skin And Tumours Of Mice", <i>Journal of Photochemistry And Photobiology B: Biology</i> , Vol. 28:213-218, (1995).	
	A41	KORELL et al., "Einsatz der Photodynamischen Lasertherapie in der Gynaekologie", <i>Gynaekol Geburtshilfliche Rundsch</i> , Vol. 35:90-97, (1995).	
	A42	UNTCH et al., "Synergistischer Effekt von Delta-Aminolaevulinsaeure und Photodynamischer Lasertherapie Anhand Eines In-Vitro-Modells Mit Dem ATP-Tumorchemosensitivitaetstest", <i>Gynaekol Geburtshilfliche Rundsch</i> , Vol. 35:85-89, (1995).	

Examiner	Date
Signature	1
Oignature	Considered
	 l l

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.

¹ Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

MODIFIED PTO/SB/08 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control

	Substitute for for	m 1449B/	PTO		Complete if Known		
	INFORMATION	DISCLO	SURE	Application Number	10/663,992		
	STATEMENT BY	Y APPLI	CANT	Filing Date	09/17/2003		
	Date Submitted: N	Marah 11	2004	First Named Inventor	James C. KENNEDY		
	Date Submitted. I	viarcii i i	, 2004	Group Art Unit	1614		
	(use as many shee	ts as ne	cessary)	Examiner Name	Unassigned		
Sheet	3	of	4	Attorney Docket Number	067286-0275		

		NON PATENT LITERATURE DOCUMENTS						
Examiner Cite No.		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.						
	A43	SZEIMIES et al., "Topische Photodynamische Therapie In Der Behandlung Oberflaechlicher Hauttumoren", Hautarzt, Vol. 46:315-318, (1995).						
	A44	WOLF et al., "Photodynamic Therapy With 5-Aminolevulinic Acid:A Promising Concept For The Treatment of Cutaneous Tumors", <i>Dermatology</i> , Vol. 190:183-185, (1995).						
	A45	YANG et al., "Evidence Of Lasting Functional Destruction Of The Rat Endometrium After 5-Aminolevulinic Acid Induced Photodynamic Ablation: Prevention Of Implantation", <i>Am. J. Obstet. Gynecol.</i> , Vol. 168(3):995-1001, (1993).						
	A46	WOLF et al., "Topical Photodynamic Therapy With Endogenous Porphyrins After Application of 5-Aminolevulinic Acid", <i>J. Am. Acad. Dermatol.</i> , Vol. 28:17-21, (1993).						
	A47	GOFF et al., "Effects Of Photodynamic Therapy With Topical Application of 5-Aminolevulinic Acid On Normal Skin Of Hairless Guinea Pigs", <i>J. Photochem. Photobiol. B: Biol.</i> , Vol. 15:239-251, (1992).						
	A48	PENG et al., "Distribution And photosensitizing Efficiency Of Porphyrins Induced by Application Of Exogenous 5-Aminolevulinic Acid In Mice Bearing Mammary Carcinoma", <i>Int. J. Cancer</i> , Vol. 52:433-443, (1992).						
	A49	SUROLIA et al., "De Novo Biosynthesis Of Heme Offers A New Chemotherapeutic Target In The Human Malarial Parasite", <i>Biochemical And Biophysical Research Communications</i> , Vol. 187(2):744-750, (1992).						
	A50	VAN HILLEGERSBERG et al., "Selective Accumulation Of Endogenously Produced Porphyrins In A Liver Metastasis Model in Rates", <i>Gastroenterology</i> , Vol. 103:647-651, (1992).						
	A51	FUKUDA et al., "Tumour-Localizing Properties Of Porphyrins. in vivo Studies Using Free And Liposome Encapsulated Aminolevulinic Acid", Comp. Biochem. Physiol., Vol. 102B(2):433-436, (1992).						
	A52	BEDWELL et al., "Fluorescence Distribution And Photodynamic Effect Of ALA-Induced PP IX In The DMH Rat Colonic Tunour Model", <i>Br. J. Cancer</i> , Vol. 65:818-824, (1992).						
	A53	REBEIZ et al., "Photodestruction of Tumor Cells By Induction Of Endogenous Accumulation Of Protoporphyrin IX: Enhancement By 1,10-Phenanthroline", <i>Photochemistry and Photobiology</i> , Vol. 55(3):431-435, (1992).						
	A54	ANDREONI et al., "Effects of HpD And Laser On Transformed and Corresponding Normal Cultured Cells: Differential Cytotoxicity As An In Vitro Model For Tumor Photochemotherapy", <i>Porphyrins In Tumor Phototherapy</i> , pp.143-155, (1983).						
	A55	ROBINO et al., "Porphyrin Metabolism In Human Neoplastic Tissues", Panminerva Medica, pp. 290-92.						

Examiner	,	Date	
Signature	'		1
Signature	,	Considered	1
·'	· · · · · · · · · · · · · · · · · · ·	1	1

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

MODIFIED PTO/SB/08 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

	Substitute fo	or form 1449B	/PTO		Complete if Known	
	INFORMATI	ON DISCLO	SURE	Application Number	10/663,992	
	STATEMEN	T BY APPLI	CANT	Filing Date	09/17/2003	
	Data Submitt	ad: Marah 1:	1 2004	First Named Inventor	James C. KENNEDY	
	Date Submitt	ed. March 1	1, 2004	Group Art Unit	1614	
	(use as many s	sheets as ne	cessary)	Examiner Name	Unassigned	
Sheet	4	of	4	Attorney Docket Number	067286-0275	

NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*	Cite Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-iss publisher, city and/or country where published.		T 6			
	A56	SAMSOEN M., Arsenal Medicamenteux Dermatologique, Pg.603-606, ISSN. 0752-5370 (1995) (Abstract).				
	A57	POTTIER et al., "Non-Invasive Technique for Obtaining Fluorescence Excitation and Emission Spectra In Vivo", <i>Photochemistry and Photobiology</i> , Vol. 44, No. 5, pp 679-687, (1986).				
	A58	MANDELL ET AL., Principles and Practice of Infectious Diseases, 4 th ed. 1995, pp. 1388, 1393-1396.				
	A59	N. NAVONE ET AL., "Porphyrin biosynthesis in human breast cancer. Preliminary mimetic <i>in vitro</i> studies", <i>Med. Sci. Res.,</i> 1988, Vol. 16, pp. 61-62, Buenos Aires, Republica Argentina.				

Examiner	Date	
Signature	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. 2See attached Kinds of U.S. Patent Documents. 3Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Skind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. Applicant is to place a check mark here if English language Translation is attached.